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## Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): anthrax

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### Abstract

Anthrax has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of anthrax to be listed, Article 9 for the categorisation of anthrax according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to anthrax. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, anthrax can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The animal species to be listed for anthrax according to Article 8(3) are several species of mammals, birds and reptiles, and susceptible herbivores and pigs as reservoir.

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## Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
1.2. Interpretation of the Terms of Reference.....	4
2. Data and methodologies.....	4
3. Assessment.....	4
3.1. Assessment according to Article 7 criteria.....	4
3.1.1. Article 7(a) Disease Profile.....	4
3.1.1.1. Article 7(a)(i) Animal species concerned by the disease.....	4
3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations.....	5
3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease.....	6
3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance.....	7
3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment.....	8
3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans.....	9
3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union.....	10
3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools.....	10
3.1.2. Article 7(b) The impact of diseases.....	11
3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy.....	11
3.1.2.2. Article 7(b)(ii) The impact of the disease on human health.....	11
3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare.....	12
3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment.....	13
3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism.....	13
3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures.....	14
3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities.....	14
3.1.4.2. Article 7(d)(ii) Vaccination.....	16
3.1.4.3. Article 7(d)(iii) Medical treatments.....	17
3.1.4.4. Article 7(d)(iv) Biosecurity measures.....	17
3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products.....	18
3.1.4.6. Article 7(d)(vi) Killing of animals.....	19
3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products.....	19
3.1.5. Article 7(e) The impact of disease prevention and control measures.....	21
3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole.....	21
3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures.....	21
3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals.....	21
3.1.5.4. Article 7(e)(iv) The environment and biodiversity.....	21
3.2. Assessment according to Article 5 criteria.....	22
3.2.1. Non-consensus questions.....	22
3.2.2. Outcome of the assessment of anthrax according to criteria of Article 5(3) of the AHL on its eligibility to be listed.....	23
3.3. Assessment according to Article 9 criteria.....	23
3.3.1. Non-consensus questions.....	26
3.3.2. Outcome of the assessment of criteria in Annex IV for anthrax for the purpose of categorisation as in Article 9 of the AHL.....	27
3.4. Assessment of Article 8.....	28
4. Conclusions.....	29
References.....	30
Abbreviations.....	32

## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel et al., 2017).

### 1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on anthrax according to the criteria of the AHL articles as follows:

- Article 7: anthrax profile and impacts
- Article 5: eligibility of anthrax to be listed
- Article 9: categorisation of anthrax according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to anthrax

## 2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017) (Table 1).

## 3. Assessment

### 3.1. Assessment according to Article 7 criteria

This section presents the assessment of anthrax according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see Section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

#### 3.1.1. Article 7(a) Disease Profile

##### 3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

*Susceptible animal species*

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

- Testudines (Testudinidae);
- Aves (Gruidae, Anatidae, Struthionidae);
- Carnivora (Ursidae, Felidae, Mustelidae, Canidae, Procyonidae, Viverridae, Eupleridae, Mephitidae);
- Proboscidea;
- Diprotodontia;
- Perissodactyla (Rhinocerotidae, Equidae);
- Artiodactyla including Bovidae (*Bison bison*), Cervidae and Suidae;
- Muridae;
- Primates.

Parameter 2 – Naturally susceptible domestic species (or family/orders)

- Bovidae (cattle, sheep, goats);
- Equidae (*Equus caballus*);
- Suidae;
- Leporidae.

### Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

- Blesbok (*Damaliscus dorcas phillipsi*);
- Mice;
- Rat;
- Monkey.

### Parameter 4 – Experimentally susceptible domestic species (or family/orders)

- Rabbit;
- Sheep;
- Goats;
- Cattle;
- Guinea pig;
- Rat;
- Mice.

### *Reservoir animal species*

A carrier state, in the sense of animals harbouring the specific organisms of a disease without overt symptoms and being capable of transmitting the infection, has not been demonstrated in anthrax (WHO, 2008).

### **3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations**

#### *Morbidity*

#### Parameter 1 – Prevalence/incidence

The following table shows the OIE – World Animal health information database (WAHID) – official data on the incidence of anthrax in Europe. The data are related to domestic species (cattle, equids, goats and sheep). The countries which are not listed have no official data. The data relate to the number of outbreaks and not to the number of individual cases.

**Table 1:** Number of outbreaks of anthrax in Europe in domestic species (Source: OIE – World Animal health information database (WAHID) – official data related to domestic species (cattle, equids, goats and sheep))

Country Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Albania	16	28	14	14	13	9	40	17	n.d.	n.d.	n.d.
Bosnia and Herzegovina	0	0	2	0	10	13	0	1	1	0	n.d.
Bulgaria	1	0	0	0	+	0	3	1	1	6	n.d.
Croatia	1	1	0	0	0	2	1	0	2	0	n.d.
Finland	0	0	1	0	0	0	0	0	0	0	n.d.
Macedonia	0	1	0	0	0	0	0	0	0	1	n.d.
France	3	5	23	23	0	0	0	1	0	0	n.d.
Georgia	3	4	7	11	9	19	27	38	21	17	10
Germany	0	0	0	2	0	0	1	0	1	0	n.d.
Greece	2	0	4	15	4	4	2	0	0	0	n.d.
Hungary	0	1	0	1	1	0	2	1	7	3	n.d.
Italy	1	+	1	0	0	26	3	0	3	1	1
Moldova	2	4	+	0	1	2	1	2	1	3	n.d.
Montenegro	0	0	0	0	3	+	1	1	0	0	n.d.
Poland	0	0	0	0	0	0	0	0	2	0	n.d.
Romania	4	2	2	2	1	1	0	0	1	0	1
Serbia	0	1	1	0	0	4	1	1	0	0	n.d.
Slovakia	0	0	0	0	3	0	2	0	1	0	n.d.

Country Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Slovenia	0	0	0	0	0	0	0	0	0	1	n.d
Sweden	0	0	0	0	0	2	0	1	0	0	n.d
Turkey	100	116	94	76	82	99	135	121	95	71	n.d
Ukraine	2	3	0	0	0	0	2	0	0	0	n.d
UK	+	0	0	0	0	0	0	0	0	1	n.d

+: Disease with an unknown number of outbreaks.

n.d: no data.

#### Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

Data not available.

#### Mortality

#### Parameter 3 – Case-fatality rate

There are no available data regarding individual cases, and the mortality rate in infected animals is high (95%). It has long been noted that in certain outbreaks a single animal species may show a higher susceptibility than another species, which is apparently similarly exposed. An inverse relationship exists between resistance to infection and susceptibility to the toxin complex as reflected in the level of the terminal bacteraemia. For example, cattle appear very prone to natural infection, but die with a high level of circulating bacteraemia indicative of a relative toxin resistance. There are regional differences in species incidence, for example in northern New South Wales, sheep and cattle are affected with equal frequency, but in southern NSW cattle are four times more likely to be affected than sheep and bovine mortality rates can be 13 times higher. In contrast to herbivores, pigs and carnivores are highly resistant to anthrax and the ingestion of large numbers of spores, as are found in infected carcasses, is generally required to induce infection in these species. However, severe mortalities have been noted in wild dogs, lions, leopards and cheetahs in spite of their innate resistance. These differences may be explained by the host species occupying different ecological niches, but those individual animals are not equally at risk due to the different grazing behaviours of the vector species, availability and density of animals, and the influence of different climates, and ecologies (Hugh-Jones and Blackburn, 2009). The variation may also be associated with different host-target potentials and strain virulence differences. Moreover mortality rates will depend on whether the animals have been vaccinated or if they have been subjected to antibiotic treatment during infection.

**Table 2:** Mortality rates during anthrax outbreaks, Italy (Fasanella et al., 2007)

Animal	Population of area	No. (%) dead animals
Cattle	≈ 7,000	81 (≈ 1.15)
Sheep	≈ 20,000	15 (≈ 0.075)
Goats	≈ 13,000	9 (≈ 0.069)
Horses	≈ 600	11 (≈ 1.83)
Red deer	45	8 (≈ 17.77)

### 3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

#### Presence

#### Parameter 1 – Report of zoonotic human cases (anywhere)

The role of *Bacillus anthracis* in causing illness, and its impact on subsistence livestock-keeping communities and the impact of sudden deaths in their herds and flocks are not, in most areas, given high priority by policy-makers in developing countries. Anthrax is transmitted by spores in contaminated soil and can infect humans via contact or consumption of dead animals or animal products. Contamination of pasture is the source of most animal cases in endemic countries. There are no official data on cases of human anthrax, because they are extremely rare. In countries in which the animal anthrax is endemic, it is possible that some humans who are in contact with animals (farmers) or parts of animal (butchers) can contract anthrax through contact with an infectious dose of spores of



*Bacillus anthracis*, but it is a very rare event. In animals, the disease is almost always fatal (95% mortality rate), and vaccination is the only realistic basis for effective control. Man is usually resistant to acquiring infection, but when infected he may show three different clinical forms: the cutaneous, the respiratory and the intestinal form.

**The cutaneous form** begins with the formation of classic malignant pustules, most often localised on face, neck, arms, hands or legs. Most frequently infection results from exposure through specific high-risk occupations; that is, farmers, butchers, tanners, wool carders, shearers and veterinarians. The most common exposure comes from skinning and butchering cattle which were either sick, or had died from anthrax. At the point of entry of the *B. anthracis*, through a pre-existing scratch, there is firstly a skin redness, which then turns into a papule. Characteristically, this lesion area is not painful. The surrounding area appears to be hyperaemic and oedematous. The papule develops into vesicles that break spontaneously, or as a result of scratching, and, eventually, the site of the lesion becomes covered with a black eschar or scab. Sometimes, the regional lymph nodes can be involved. Cutaneous anthrax is easily treatable with appropriate antibiotics, but if a pustule is neglected it may result in systemic disease through septicaemia, which can result in fatalities. Some 10% of untreated cutaneous cases may die.

**Intestinal anthrax** results from the consumption of contaminated meat. Its symptoms include nausea, loss of appetite, vomiting and fever followed by abdominal pain, vomiting of blood, severe diarrhoea, lesions and soreness in the throat, difficulty in swallowing and marked swelling of the neck and regional lymph nodes. Intestinal anthrax results in death in 25–60% of cases. The intestinal form occurs less frequently and occurs in those developing countries where food safety controls measures are de facto non-existent or less well developed. Thorough cooking will kill the vegetative cells and prior exposure to *B. anthracis* does provide some immunity, so the rate of disease development in any case of exposure is variable.

**The respiratory or pulmonary form** is a cause of an atypical haemorrhagic pneumonia – starting with flu-like symptoms, characterised by fever, muscle pains, coughing, red nose and bloody sputum. Untreated cases are usually fatal. A study of several confirmed cases of inhalational anthrax caused by an intentional release of *B. anthracis* in the United States showed that the median incubation period from the time of exposure to onset of symptoms was 4 days (range: 4–6 days). Symptoms at initial presentation included fever or chills, sweats, fatigue or malaise, a minimal or non-productive cough, dyspnoea and nausea or vomiting. All 10 patients had abnormal chest X-rays; visible abnormalities in x-ray studies showed infiltrates, pleural effusion and mediastinal widening. Computer tomography of the chest was performed on eight patients, and mediastinal lymphadenopathy was present in seven. Forty-one cases of documented inhalational anthrax from the Sverdlovsk epidemic of 1979 showed that the lesions that were the most severe and apparently of the longest duration were in the mediastinal lymph nodes and mediastinum. There and elsewhere, peripheral transudate surrounded a fibrin-rich oedema; necrosis of arteries and veins was the most likely source of large haemorrhages displacing tissue or infiltrating tissues, respectively; and apoptosis (destruction) of lymphocytes was observed. Respiratory function was compromised by mediastinal expansion, and by significant amounts of pleural effusion and haematogenous and retrograde lymphatic vessel spread of *B. anthracis* into the lungs with consequent pneumonia. The central nervous system and intestines manifested similar haematogenous spread, vasculitis, haemorrhages and oedema (WHO, 2008).

#### 3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

##### Parameter 1 – Resistant strain to any treatment even at laboratory level

Anthrax has been considered a potential biological weapon for at least 60 years. Prevention of anthrax infection relies on serial vaccinations and prolonged antibiotic treatment against the infection. Owing to limited global availability of the anthrax vaccine, most treatment strategies utilise antibiotics. Penicillin G, doxycycline and ciprofloxacin have been for long time the chosen drugs (recommended by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA)) for first-line treatment of all forms of anthrax disease in humans. Combinations of these drugs were used to treat the recent US cases; yet, historically, penicillin has been the antimicrobial agent most commonly used for treating anthrax worldwide. The emergence of natural antibiotic resistance is a global phenomenon that is on the increase and is partially related to long-term antibiotic therapy (for 60 days or more). While there have been no reports of naturally occurring ciprofloxacin- or doxycycline-resistant *B. anthracis* strains, naturally occurring penicillin G-resistant *B. anthracis* isolates have been reported in the literature (Bradaric and Pundapolic, 1992; Lalitha and Thomas, 1997). Tests



of 50 historical *B. anthracis* isolates and 15 isolates from the recent human anthrax cases in the United States indicate widespread susceptibility to  $\beta$ -lactam-containing compounds with one exception. Out of the 65 strains tested, one strain, isolated from a human case of anthrax in 1974, was  $\beta$ -lactamase positive and penicillin resistant. In another survey, 7 out of 44 isolates from carcasses and soil derived from a region of South Africa in which anthrax was endemic were resistant to penicillin G (Odendaal et al., 1991). A third survey of isolates recovered in France, including 1 isolate from a human, 28 from animal sources, and 67 from other environmental sources, revealed resistance to penicillin G and amoxicillin in 11.5% of the isolates (Cavallo et al., 2002). Bacterial resistance to  $\beta$ -lactam antibiotics is most commonly attributed to the synthesis of  $\beta$ -lactamases, which are enzymes that hydrolyse amides, amidines, and other carbon–nitrogen bonds in cyclic amides. The mechanism underlying  $\beta$ -lactam resistance is due to the presence of two  $\beta$ -lactamases genes, *bla1* and *bla2*, with *bla1* being a penicillinase and conferring high-level resistance to ampicillin, amoxicillin and penicillin G, while *bla2* is a cephalosporinase conferring low-level resistance to ceftriaxone, cefazolin, ceftiofur and cefotetan (Athamna et al., 2004). Furthermore, *in vitro* studies have shown that *B. anthracis* strains, isolates found from locations diverse in time, space, and genotype – can all develop resistance to a wide range of antibiotics – including ciprofloxacin, doxycycline and  $\beta$ -lactam antibiotics, and also levofloxacin, gatifloxacin, tetracycline, trimethoprim, linezolid, chloramphenicol, rifampicin and clindamycin. The mechanism of resistance of *B. anthracis* has not been fully explored. However, it is known that strains that are fluoroquinolone resistant, owe this resistance to the development of mutations in *gyrA*, *parC* and *gyrB* as have been described by Price et al. (2003).

### 3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

#### *Animal population*

##### Parameter 1 – Duration of infectious period in animals

Anthrax in animals usually shows a rapid progression with a fatal outcome. Clinical signs of the disease in herbivores are visible only within a few hours before death. The incubation period for anthrax in susceptible laboratory animals normally ranges between about 36 and 72 h regardless of the route of infection (Beyer and Turnbull, 2009). The range of incubation period appears to be wider in susceptible livestock and, for the purposes of trade restrictions, OIE specifies a period of 20 days (OIE, online). The first sign of anthrax in a herd or flock is usually the sudden death of one or more of the animals. On close observation, affected animals become distressed during the final systemic phase of infection. Swellings in the submandibular fossa may be apparent and body temperatures may rise. The systemic phase in susceptible animals may only last a few hours and the animal finally becomes comatose and dies; these events may take longer in immunised animals or in more resistant species, attributable to lower terminal bacteraemia and reduced levels of circulating toxin in such animals. The only clinical symptom, which is usually detectable one or 2 days before death, is pyrexia (a fever). The carcasses of animals dying from anthrax are reservoirs of spores. The spores which pass from the carcasses to the soil are very durable and can remain quiescent and viable for many years.

##### Parameter 2 – Presence and duration of latent infection period

Anthrax is a severe acute disease. Instances of carrier state, prolonged incubation or chronic infection have been reported, but appear to be rare and unusual (WHO, 2008). Experimental studies in monkeys and laboratory mice aimed at improved understanding of inhalation anthrax have shown that inhaled spores may lie dormant in the lung of monkeys for weeks before being cleared by alveolar macrophages, showing no evidence of germination until they are within the macrophages (Barnes, 1947; Henderson et al., 1956; Widdicombe et al., 1956; Ross, 1957; Friedlander et al., 1993). Insects could be vehicles for spores of anthrax spores. Insects (such as horse flies) are considered passive carriers and do not establish any direct relation to the *B. anthracis* (Hugh-Jones and Blackburn, 2009).

##### Parameter 3 – Presence and duration of the pathogen in healthy carriers

See Section 3.1.1.4 Parameter 2.

## Environment

### Parameter 4 – Length of survival of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

Soil stained with terminally haemorrhaged blood and with non-haemorrhagic fluids exhibited high levels of *B. anthracis* spore contamination (ranging from 103 to 108 spores/g (Bellan et al., 2013)).

The ecological and genetic factors that govern the persistence of anthrax reservoirs in the environment are still obscure (Schuch and Fischetti, 2009). There is a need for additional research on the conditions that favour *B. anthracis* survival in soil, e.g. to study whether *B. anthracis* undergoes a growth cycle in soil, or investigate the potential for transfer of *B. anthracis* virulence genes to other soil microorganisms (Pepper and Gentry, 2002). For example, Dey et al. (2012) demonstrated that under simulated environmental conditions amoebas can contribute to the amplification of *B. anthracis*.

In many parts of the world, the *B. anthracis* is endemic in soils, where it causes sporadic disease in livestock. These soils are typically rich in organic matter and calcium that promote survival of resilient *B. anthracis* spores. Outbreaks of anthrax tend to occur in warm weather following rains that are believed to concentrate spores in low-lying areas where runoff collect (Dey et al., 2012).

It has been reported that anthrax spores have survived in dry soil for 60 years (Wilson and Russell, 1964). The longest survival claim is probably the one on regarding anthrax spores from bones retrieved during archaeological excavations at a site in the Kruger National Park, South Africa, that were estimated by carbon-dating to be  $200 \pm 50$  years old (De Vos, 1990). The data from annual sampling between 1946 and 1969 of a contaminated site on Gruinard Island, Scotland (where an estimated  $4 \times 10^{14}$  spores were dispersed by explosive means in 1942 and 1943 during the Second World War) predicted to decay until undetectable by 2050 (Manchee et al., 1990).

Environmental isolates of *B. anthracis* from sites with a history of anthrax spore contamination in the distant past quite frequently lacked the pXO2 DNA plasmid and, less frequently, both pXO1 and pXO2 DNA plasmids. It is hypothesised that, under 'stressful environmental conditions' such as within sewage or in the harsh semidesert circumstances (such as those found in the Etosha National Park in Namibia for example) *B. anthracis* could spontaneously lose one or both virulence plasmids (WHO, 2008). When first cultured, the isolates were a mixture of capsulating and non-capsulating cells, possibly representing a population in the transition stage. However, the precise causes and events responsible for the loss of one or other of the plasmids and the time or times during the germination, outgrowth, multiplication and resporulation at which these events occur is not known (Turnbull et al., 1992).

### **3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans**

#### *Routes of transmission*

#### Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

Anthrax does not typically spread from animal to animal or from person to person. The typical route of infection in animals is grazing on soils contaminated with spores of *B. anthracis*.

#### Parameter 2 - Type of routes of transmission between animals and humans (direct, indirect, including food-borne)

Humans can become infected by eating meat from infected animals or manipulating animal products such as hides, hair, wool or bones that could contain anthrax spores.

#### *Speed of transmission*

#### Parameter 3 – Incidence between animals and, when relevant, between animals and humans

Transmission from animals to humans depends on the social conditions of the country in which outbreaks of anthrax occurred. In developed countries, it is very rare that animal anthrax outbreaks involve humans, and usually the infection to humans occurs during the slaughter of infected animals. The result is that the ratio of animal/human cases is in favour of animals cases. In poor or developing countries, slaughtering animals during the pre-agonic phase of the disease (before the animal shows full clinical symptoms) can occur and result in the sale of infected meat. This can lead the opposite

situation to that above (many human cases from few animals cases), if the infected meat is sold to a large number of consumers (Fasanella et al., 2013b).

Parameter 4 – Transmission rate (beta) (from  $R_0$  and infectious period) between animals and, when relevant, between animals and humans

Data is not available.

### **3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union**

*Presence and distribution*

Parameter 1 – Map where the disease is present in EU

See Table 1.

Parameter 2 – Types of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

The epidemiological occurrence of anthrax depends on the country. In some countries, the disease is absent or seen only sporadically (for example in Italy and Greece). In other countries, anthrax is endemic (for example, Albania, Georgia, Turkey). In the countries in which the disease is present, epidemics are a possibility, and recently, it has been proposed that there are three different types of outbreaks (Fasanella et al., 2014). The first is a classic sporadic outbreak. This form occurs in areas where anthrax is enzootic and infection takes place because of contaminated pastures. These outbreaks are sporadic and usually involve initially only 1–3 animals. The second type is an atypical outbreak and this form is associated with the use of forages (e.g. hay, silage) produced on contaminated land or with products of animal origin such as inadequately sterilised meat and bone meals derived from the infected carcasses. The third type is an epidemic outbreak and this form is an evolution of the classic sporadic form due to the activities of *Haematophagus* flies. Tabanid flies feeding on moribund animals, especially during the bacteraemic phase, are able to transfer the pathogen to healthy animals in the same or neighbouring herds or flocks, causing a disease characterised by extensive oedema.

*Risk of introduction*

Infection is already present in Member States (MSs).

### **3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools**

*Diagnostic tools*

Parameter 1 – Existence of diagnostic tools

As described in 'Anthrax in Humans and Animals, 4th Edition' (WHO, 2008), several techniques can be used for the diagnosis of anthrax. With regard to the confirmation of bacterial species, after isolation of bacteria from sample, it is necessary overnight incubation at 35–37°C on horse or sheep blood agar (BA). Colonies of *B. anthracis* are white or grey-white and non-haemolytic, 2–4 mm in diameter, with a slightly moist, matt appearance. Use of selective media for the isolation of *B. anthracis*, like polymyxin lysozyme EDTA thallous acetate (PLET) agar and trimethoprim sulfamethoxazole methanol polymyxin (TSMP) in blood agar may facilitate growth; the latter can be useful to discriminate haemolytic colonies from non-haemolytic. After bacterial DNA extraction, polymerase chain reaction (PCR) for *pag* and *cap* genes may be used for species confirmation. After isolation of bacteria from sample, also the matrix assisted laser desorption ionization-time of flight (MALDI TOF) technique may also be used in order to identify the species (Lasch et al., 2009). Regarding serological tests, two types of serological assays, an anti-protective antigen (PA) immunoglobulin G (IgG) enzyme-linked immunosorbent assay (ELISA) and the anthrax toxin neutralising assay (TNA) can be used to determine the antibody levels (Pitt et al., 1999).

## *Control tools*

### Parameter 2 – Existence of control tools

Animal anthrax has a rapid disease progression, in most cases with a fatal outcome, so it is quite difficult to implement control measures. However, control could be performed by vaccinating susceptible animals and carrying out a movement control of animals. Another control tool is the execution of the biosecurity measures in case of outbreak (Fasanella et al., 2014). As regards the control of the environment in areas known to be contaminated, the Ground Anthrax Bacillus Refined Isolation (GABRI) method (Fasanella et al., 2013a) is a useful technique for the detection and quantification of anthrax spores in the soil, especially in proximity of the burial sites.

### **3.1.2. Article 7(b) The impact of diseases**

#### **3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy**

##### *The level of presence of the disease in the Union*

#### Parameter 1 – Number of MSs where the disease is present

See Table 1.

##### *The loss of production due to the disease*

#### Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

There are no official data but considering the few cases of animal anthrax and considering the few dead animals, the proportion of production losses can be estimated as low.

#### **3.1.2.2. Article 7(b)(ii) The impact of the disease on human health**

##### *Transmissibility between animals and humans*

#### Parameter 1 – Types of routes of transmission between animals and humans

Contact with infected meat, ingestion of infected meat, contact with parts of animal which died because of anthrax, contact with live animals which are infected.

#### Parameter 2 – Incidence of zoonotic cases

Cases of human anthrax are rare; however, they can occur in countries where the animal anthrax is endemic.

##### *Transmissibility between humans*

#### Parameter 3 – Human to human transmission is sufficient to sustain sporadic cases or community-level outbreak

No.

#### Parameter 4 – Sporadic, endemic, epidemic, or pandemic potential

Possible epidemic case only in the case of deliberate release of anthrax spores in the environment (bioterrorism).

##### *The severity of human forms of the disease*

#### Parameter 5 – Disability-adjusted life year (DALY)

Data not available

##### *The availability of effective prevention or medical treatment in humans*

#### Parameter 6 – Availability of medical treatment and their effectiveness (therapeutic effect and any resistance)

The approach to prevention and treatment of anthrax differs from that applied for other bacterial infections. The production of toxin, potential for antimicrobial drug resistance, frequent occurrence of meningitis, and presence of latent spores must be taken into account when selecting post-exposure prophylaxis (PEP). A combination of antimicrobial drugs for treatment of anthrax is more likely to be

curative than antimicrobial drug monotherapy. There is also a theoretical benefit for combined use of bactericidal and protein synthesis inhibitor agents. Bactericidal agents can have an immediate killing effect. However, the high rates of illness and death seen with anthrax are caused, in part, by *B. anthracis* exotoxin production. *In vitro* toxin production is inhibited earlier by protein synthesis inhibitors earlier than by bactericidal agents. Patients hospitalised for systemic anthrax should be immediately treated with a combination of broad-spectrum intravenous antimicrobial drug treatment pending confirmatory test results because any delay may prove fatal. After treatment, uncomplicated cutaneous anthrax has a mortality rate of < 2%. However, even with antimicrobial drug treatment and modern critical care, injection, gastrointestinal, and inhalation anthrax have mortality rates of 28%, ≥ 40%, and 45%, respectively. Anthrax meningitis is nearly always fatal, even with treatment. The CDC issued updated guidelines on anthrax PEP and treatment in non-pregnant and pregnant adults (Meaney-Delman et al., 2014). Recommendations include the following:

- All individuals exposed to aerosolised *B. anthracis* spores should receive a full 60 days of PEP antimicrobial drugs, regardless of their vaccination status;
- Ciprofloxacin, levofloxacin and doxycycline are approved by the FDA for PEP for inhalation anthrax in adults aged 18 years or older; ciprofloxacin and doxycycline are first-line treatments. Alternative antimicrobial drugs that might be used for PEP if first-line agents are not tolerated or are unavailable include levofloxacin and moxifloxacin; amoxicillin and penicillin VK if the isolate is penicillin susceptible; and clindamycin. The antimicrobial drug linezolid cannot be used for extended periods. Also, the risk for development of resistance must be kept in mind if using  $\beta$ -lactam drugs;
- Treatment for anthrax meningitis should include at least three antimicrobial drugs with activity against *B. anthracis*, at least one of which should have bactericidal activity, and at least one of which should be a protein synthesis inhibitor. For patients suspected to have systemic anthrax, antitoxin should be added to combination antimicrobial drug treatment;
- Uncomplicated cutaneous anthrax can be treated with a single oral agent; fluoroquinolones (ciprofloxacin, levofloxacin and moxifloxacin) and doxycycline are equivalent first-line drugs;
- Treatments for pregnant, post-partum and lactating women are generally the same as those for non-pregnant patients.

#### Parameter 7 – Availability of vaccines and their effectiveness (reduced morbidity)

The two main types of anthrax vaccine for human use are indicated for active immunisation for the prevention of disease caused by *B. anthracis*, in persons 18–65 years of age at high risk of exposure. The vaccines are prepared from a cell-free filtrate of *B. anthracis* that contains antigenic proteins, which are adsorbed or precipitated using an aluminium-based adjuvant. The principal active ingredient is the protective antigen (PA) component of the anthrax toxin complex. These vaccines include Anthrax Vaccine Adsorbed (AVA) and Anthrax Vaccine Precipitated (AVP).

- AVA, adsorbed onto aluminium hydroxide, was first licensed in the USA in 1972 and is administered intramuscularly in five doses over a period of 18 months (Wright et al., 2010). The strain used to prepare the vaccine is a toxigenic, non-encapsulated strain known as V770-NPI-R.
- AVP, precipitated onto aluminium potassium phosphate, was first licensed in the UK in 1979 and is administered intramuscularly in four doses over a period of 8 months (32 weeks). The strain used to prepare the vaccine is a Sterne strain 34F2.

(WHO, 2012a,b)

### **3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare**

#### Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

The symptomatology changes depending to the species. In bovine anthrax, may be hyperacute or acute. In the hyperacute form, animals are frequently found dead without the owner noting any obvious premonitory signs. This usually occurs at the beginning of an outbreak. In animals where clinical signs are observed, this will include fever, wheezing, congestion of mucous, muscle tremors and convulsions. In the acute form, the disease is characterised by septicaemia, high fever (41–42°C), tachypnoea, and congested and haemorrhagic mucous membranes. Initially, the animal may be excited, but this is followed by major depression. In sheep, the fulminant form is most common: the animals can die in a few minutes with convulsions. In equines, the disease develops with colic syndrome and septicaemia associated with muscle tremors, sensory depression, a very high fever,



cyanosis, tachypnoea and tachycardia. Pigs are more resistant and the disease is usually subclinical (Smith, 1973). The carnivores are fairly resistant, but if affected they show signs of acute gastroenteritis and oropharyngitis, which is due to ingestion of large volumes of infected meat (Fasanella et al., 2010).

### 3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

#### Biodiversity

##### Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

All species related to the Orders/Families mentioned in Section 3.1.1.1 'Susceptible animal species' could become infected.

##### Parameter 2 – Mortality in wild species

The mortality is high (> 95%) in herbivores and low in carnivores because serological evidence seems to indicate that naturally acquired anthrax antibodies are rare in herbivores but common in carnivores (Hugh-Jones and de Vos, 2002). In the wild, anthrax does not affect all herbivorous species equally, and there is an apparent susceptibility to the disease for particular species in some regions. Zebras, for example, are the most commonly affected in the Etosha National Park in northern Namibia, with kudu only occasionally affected – with 45% of recorded cases being in zebra vs 0.8% for kudu (Lindeque and Turnbull, 1994). In the Kruger National Park, South Africa, the kudu is the principal host, accounting for > 50% of all recorded anthrax cases (De Vos, 1990). Grazing, browsing and flies are the main variables in these different regions; flies are the vectors of spores from dead carcasses to foliage in some vicinities. In Texas, goats and white-tailed deer frequent the same areas but, if horseflies are transmitters of the disease, they fail to infect the goats. In Europe, there is only limited data (Hugh-Jones, 2004).

#### Environment

##### Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

One of the major characteristics of *B. anthracis* spores is to be very persistent in the environment, and it is evident that the spores can remain viable in soil up to hundreds of years. Anthrax spores survive best in black steppe soils rich in organic matter and calcium. The persistence of spores in the soil exposes grazing animals at higher risk of anthrax. The major source of spores in the soil is the presence of material from infected carcasses.

### 3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Bioterrorism can be defined as the deliberate release of pathogenic microorganisms or parts thereof, in order to cause panic, terror, death or illness in the population, for political, religious or economic claims. From a strictly academic perspective, this kind of terrorism appears a derivative of a real biological warfare: both use the same weapons, but with different purposes, methods of dissemination and means. The biological weapon is based on the use of biological aggressive, that is, the microorganisms and chemical substances produced from these ones (toxins), capable of inducing a state of disease in humans, animals or plants and/or cause the deterioration of the materials that can be used for military purposes for their biological and technical characteristics. Anthrax has many of the requirements to be qualified as an agent for potential bioterrorist use:

(1) virulence adequate to the intended use; (2) low minimal microbial charge; (3) low median lethal dose; (4) period of incubation known and adapted to the intended use; (5) high storage stability; (6) adequate persistence to the intended use; (7) difficulty of detection/identification; (8) ease of production in significant quantities; (9) ease of dissemination; (10) controllability, by the attacker, of the spread of the disease; (11) little or no sensitivity to known pharmacological and immunological treatment and prophylaxis. The *B. anthracis* spores represent one of the most advanced forms of resistance in nature. In the form of spore, *Bacillus* can survive outdoors for many years. For its ease of production and for the fact that the spores are well preserved without the need of having to resort to any type of particular form of protection, *B. anthracis* has been studied for its potential use as a bacteriological weapon of mass destruction. Although it has recently been revealed that the Russian programme on biological weapons included anthrax genetically not modified (Sahl et al., 2016), it is suspected that spore manipulations were carried out to make them more volatile and favour the air flotation time in order to have a greater chance of being inspired by the people. There were two

incidents of bioterrorism where anthrax was used. The first occurred in Tokyo in the 1990s by the religious sect Aum Shinrikyo that had produced anthrax and had sprayed it in a restricted area of the city. Fortunately, this incident had no consequences simply because the strain used for the attack was the vaccination one. Dramatically famous is instead the episode of 2001, which occurred in the United States and related to the epidemic of cutaneous and pulmonary anthrax caused by the delivery of letters containing anthrax spores in Florida and in Washington. According to official figures of the time, 22 people (but 68 according to recent studies) were affected by spores in the letters, and five of them died. The anthrax Ames strain, responsible for the morbid forms, was the same used in various military labs and production sites of biological weapons in the United States prior to their disposal, which took place unilaterally in the late sixties. The destructive potential was huge, just think that one gram of spores contained  $10 \times 10^{12}$  spores and that the lethal dose for humans is 8,000–10,000 spores.

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

It is listed.

Parameter 2 - Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

It is listed.

Parameter 3 - Included in any other list of potential bio- agro-terrorism agents

It is listed.

### **3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures**

#### **3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities**

##### *Availability*

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

Diagnostic techniques which are OIE certified are described in Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2016 (OIE, 2012). With regard to identification of the agent, OIE suggests isolation of the bacterial agent from fresh specimens through growing of agent on horse or sheep blood agar. After overnight incubation at 37°C, *B. anthracis* colonies are grey–white to white, 0.3–0.5 cm in diameter, non-haemolytic, with a ground-glass surface and very tacky when teased with an inoculating loop. Two more tests described by OIE for confirming the identity of *B. anthracis* are gamma phage lysis and penicillin susceptibility. Regarding the immunological detection, the OIE suggests Ascoli test (Ascoli, 1911), while some success has been achieved with immunofluorescence for capsule observation in the research situation (Ezzell and Abshire, 1996). Confirmation of virulence can be carried out using PCR (WHO, 2008).

##### *Effectiveness*

Parameter 2 – Se and Sp of diagnostic test

Microbiological tests allow for the isolation and identification of *B. anthracis* with high sensitivity and specificity, but to be sure of the result, it is always necessary to perform biomolecular analysis.

##### *Feasibility*

Microbiological test, biomolecular test and serological test are sold by many companies.



Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

See Tables 3, 4 and 5.

**Table 3:** Blood or tissues samples from fresh anthrax-infected carcasses

Tested material: Blood or tissues from fresh anthrax-infected carcasses					
Direct microscopy analysis on samples	Isolation procedures		Confirmatory tests on isolated colonies		
	Treatment of material for isolation of <i>B. anthracis</i>	Culture media	Microscopy analysis	Gamma phage lysis and penicillin susceptibility	Specific PCR for chromosome, pXO1 and pXO2 plasmids
<b>Polychrome methylene blue – McFadyean's reaction</b> The capsule of virulent encapsulated <i>B. anthracis</i> stains pink, whereas the bacillus cells stain dark blue. However, if the animal has been dead more than 24 h, the capsule may be difficult to detect. Gram and Giemsa stains do not reveal the capsule.	No treatment is required	<b>Blood agar PLET TMSP 5% sheep blood agar</b> Colonies are grey-white to white, 0.3–0.5 cm in diameter, non-haemolytic, with a ground-glass surface, and very tacky when teased with an inoculating loop.	<b>Polychrome methylene blue. Gram staining</b> Confirmation of <i>B. anthracis</i> should be accomplished by the demonstration of a capsulated, spore-forming, Gram-positive rod in blood culture. The absence of motility is an additional test that can be done.	Indicative but not definitive	Definitive diagnosis

PCR: polymerase chain reaction; PLET: polymyxin lysozyme EDTA thallous acetate; TSMP: trimethoprim sulfamethoxazole methanol polymyxin.

**Table 4:** Bone meal, hides and turbinate of old decomposed carcasses samples of *B. anthracis*

Tested material: Bone meal, hides, turbinate of old decomposed carcasses					
Direct microscopy analysis on samples	Isolation procedures		Confirmatory tests on isolated colonies		
	Treatment of material for isolation of <i>B. anthracis</i>	Culture media	Microscopy analysis	Gamma phage lysis and penicillin susceptibility	Specific PCR for chromosome, pXO1 and pXO2 plasmids
Not applicable	<b>Heat treatment</b> To reduce environmental contaminants the sample is blended in two volumes of sterile distilled or deionised water or a 0.1% of a Tween 20 water solution. Washed for 20 min and then placed in a water bath at $62.5 \pm 0.5^\circ\text{C}$ for 30–60 min.	<b>PLET TMSP 5% sheep blood agar</b> Colonies are grey-white to white, 0.3–0.5 cm in diameter, non-haemolytic, with a ground-glass surface, and very tacky when teased with an inoculating loop. The 5% sheep blood agar is not recommended because the absence of antibiotic can promote the growth of Gram-negative contaminants.	<b>Polychrome methylene blue Gram staining</b> Confirmation of <i>B. anthracis</i> should be accomplished by the demonstration of a capsulated, spore-forming, Gram-positive rod in blood culture. The absence of motility is an additional test that can be done.	Indicative but not definitive	Definitive diagnosis

PCR: polymerase chain reaction; PLET: polymyxin lysozyme EDTA thallous acetate; TSMP: trimethoprim sulfamethoxazole methanol polymyxin.

**Table 5:** Environmental samples of *B. anthracis*

Tested material: Environmental samples					
Direct microscopy analysis on samples	Isolation procedures		Confirmatory tests on isolated colonies		
	Treatment of material for isolation of <i>B. anthracis</i>	Culture media	Microscopy analysis	Gamma phage lysis and penicillin susceptibility	Specific PCR for chromosome, pX01 and pX02 plasmids
Not applicable	<b>Heat treatment</b> To reduce environmental contaminants the sample is blended in two volumes of sterile distilled or deionised water or a 0.1% of a tween 20 water solution. Washed for 20 min and after a short sedimentation remove the supernatant. Then placed in a water bath at $62.5 \pm 0.5^\circ\text{C}$ for 30–60 min	<b>PLET TMSP 5% sheep blood agar</b> Colonies are grey–white to white, 0.3–0.5 cm in diameter, non-haemolytic, with a ground-glass surface, and very tacky when teased with an inoculating loop. The 5% sheep blood agar is not recommended because the absence of antibiotic can promote the growth of Gram-negative contaminants	<b>Polychrome methylene blue Gram staining</b> Confirmation of <i>B. anthracis</i> should be accomplished by the demonstration of a capsulated, spore-forming, Gram-positive rod in blood culture. The absence of motility is an additional test that can be done	Indicative but not definitive	Definitive diagnosis

PCR: polymerase chain reaction; PLET: polymyxin lysozyme EDTA thallos acetate; TSMP: trimethoprim sulfamethoxazole methanol polymyxin.

### 3.1.4.2. Article 7(d)(ii) Vaccination

#### Availability

Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

Vaccine: Live Spore Sterne Vaccine.

Strain: *B. anthracis* Sterne 34 F2.

Quality characteristic of Sterne strain: acapsulated toxigenic.

Genetic characteristic of Sterne strain: pX01+/pX02-.

Vaccine formulation: live spores suspended in glycerol with saponin of only saponin added as an adjuvant.

Production Manufactured in accordance with the Requirements for anthrax spore vaccine (live for veterinary use), Requirements for biological substances No. 13 (WHO, 1967), the Manual for the production of anthrax and blackleg vaccines (FAO, 1991) and the Manual of diagnostic tests and vaccines for terrestrial animals (OIE, 2012).

General recommendations: animals being vaccinated should not receive antibiotics for several (7–10) days before or after vaccination. The vaccine may be rendered ineffective, for example, in cattle on antibiotics for growth promotion or receiving anti-mastitis therapy. Concerns that antibiotics may have interfered with vaccine efficacy, the animals may be revaccinated after a period of 2 weeks.

Parameter 2 – Availability/production capacity (per year)

Data not available for European Community (in Italy the production is on average 100,000 doses).

#### Effectiveness

Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

Experimentation has shown that the monovalent rPA vaccine (rPA) and trivalent vaccine (TV, containing rPA and two inactive mutants of LF and EF) protected 100% of rabbits challenged with

200LD50 of the virulent strain *B. anthracis* 0843 1 week later the vaccination. The same work has shown that the vaccine Sterne protected 80% of rabbits 1 week after the vaccination (Fasanella et al., 2008).

#### Parameter 4 – Duration of protection

From 6 months to 1 year.

#### *Feasibility*

#### Parameter 5 – Way of administration

Subcutaneous to intramuscular.

### **3.1.4.3. Article 7(d)(iii) Medical treatments**

#### *Availability*

#### Parameter 1 – Types of drugs available on the market

In humans (Table 6):

**Table 6:** Types of drugs available on the market for humans

<b>Drug</b>	<b>Method of Administration</b>	<b>Effectiveness</b>	<b>Production capacity (per year)</b>
<b>Penicillin G procaine</b>	Oral, intravenous	<b>Bactericidal agents</b> (inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV (both Type II topoisomerases), which are required for bacterial DNA replication, transcription, repair, and recombination)	Data not available
<b>Ciprofloxacin</b>	Oral, intravenous	<b>Bactericidal agents</b> (inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV (both Type II topoisomerases), which are required for bacterial DNA replication, transcription, repair, and recombination)	Data not available
<b>Doxycycline</b>	Oral, intravenous	<b>Protein synthesis inhibitor</b>	Data not available

In animals:

Early treatment and vigorous implementation of a preventive program (annual vaccination) are essential to reduce losses among livestock. Livestock at risk should be immediately treated with a long-acting antibiotic to stop all potential incubating infections. This is followed by vaccination ~ 7–10 days after antibiotic treatment. Any animals becoming sick after initial treatment and/or vaccination should be retreated immediately and revaccinated a month later. Simultaneous use of antibiotics and vaccine is inappropriate, because available commercial vaccines for animals are live vaccines. Animals should be moved to another pasture away from where the bodies had lain and any possible soil contamination. Suspected contaminated feed should be immediately removed. Domestic livestock respond well to penicillin if treated in the early stages of the disease. Oxytetracycline given daily in divided doses also is effective. Other antibacterials, including amoxicillin, chloramphenicol, ciprofloxacin, doxycycline, erythromycin, gentamicin, streptomycin and sulfonamides also can be used, but their effectiveness in comparison with penicillin and the tetracyclines has not been evaluated under field conditions.

### **3.1.4.4. Article 7(d)(iv) Biosecurity measures**

#### *Availability*

#### Parameter 1 – Available biosecurity measures

The measures required to reach the maximum level of 'biosafety' are not necessarily the same as those needed to reach the maximum level of 'biosecurity'. To achieve this last one, suitable measures must be adopted, like controlled access and barriers to laboratories, security measures on the personnel employed, strict procedures for the transportation or traceability of biological agents within

and most of all outside the laboratory, to avoid the loss or theft of the preserved agents and toxins. These activities involve checks, and therefore regulations and restrictions, not only locally, but also nationally and internationally. Therefore it seems crucial, in order to reach the highest level of 'biosecurity', to know which potential dual-use agents are used in the various laboratories, in which quantity, their exact location, their movements and how they are used for positive purposes. Clinical specimens and cultures of *B. anthracis* should be handled at biosafety level 3. Vaccination of laboratory personnel is recommended. Protection for veterinarians and other animal handlers involves wearing gloves, and other protective clothing when handling specimens from suspected anthrax carcasses and never rubbing the face or eyes. The risk of gastrointestinal anthrax may arise if individuals eat meat from animals infected with anthrax. The risk of inhaling infectious doses becomes significant in occupations involving the processing of animal by products for manufacturing goods (industrial anthrax). These include the tanning, woollen, animal hair, carpet, bone processing and other such industries, where the potential for aerosolisation of substantial numbers of spores increases the risk of exposure to infectious doses. It is important that industrial workers use appropriate personal protective clothing and equipment and follow standard operating procedures that minimise the risk of transmission. Efficient air extraction equipment should be positioned over picking, combing, carding and spinning machines. Air blowing machinery should never be used for cleaning equipment due to the risk of spore dispersal (OIE, 2012).

### *Effectiveness*

#### Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Biosecurity measures have proved to be very effective in avoiding the bacteria introduction.

### *Feasibility*

#### Parameter 3 – Feasibility of biosecurity measure

All biosecurity measures are easily achievable and must be performed by personnel who work in contact with infected or potentially infected animals.

In case of animal anthrax outbreak, it is necessary a proper handling of the dead subjects and of those potentially infected. In many countries, the staff at risk (veterinarians, butchers, shearers, breeders) are not vaccinated and therefore they should follow the following instructions:

- Do not touch the carcass of animals with bare hands.
- In the case of very hairy animals, avoid disturbing hair that can become airborne and be inhaled (the hairs are often the vehicle of spores). In this case, wetting the dead animal's body with formalin or peracetic acid may help to reduce the spores in the environment and reduce the dispersion of the hair.
- Wear two pairs of gloves, Tyvec jumpsuit with a hood, masks with filters from 0.45 m, plastic shoes.
- In the case of live animals and animal suspected of infection.
- Do not touch the animals with bare hands during the temperature control step, blood sampling and vaccination.
- Always wear at least two pairs of gloves, Tyvec jumpsuit with a hood, masks with filters from 0.45 m, plastic shoes.
- Take the blood sample in a controlled way to minimise the risk of self-injury (needle stick injury).

In all cases, the operator will undress (with assistance) after the procedure, and all protective layers will be destroyed immediately by burning (on location).

### **3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products**

### *Availability*

#### Parameter 1 – Available movement restriction measures

Anthrax is a disease whose clinical course is very rapid and often the animals are found dead in the barn or on pasture. In the event of an outbreak affecting grazing animals (animal found dead on the pastures), the animals should be immediately brought into the stable and further movements avoided. The animals must be immediately vaccinated. Before vaccination, it is necessary to check the body temperature and, if this is regular, the first vaccination should be made. In the case in which the body temperature is not regular (fever), then the animals must be isolated and treated in advance with

antibiotic therapy. Vaccination should then be performed after not less than 1 week since the last antibiotic treatment. A booster vaccination is recommended 14 days after the first vaccination. Animals can be moved again not earlier than 10 days after the second vaccination intervention.

In the event of an outbreak affecting tethering animals (stabled), it is recommended not to allow any movement. The forage being fed must be suspected and thus it should be replaced with alternative forage of a different origin. The animals must be immediately vaccinated. Before vaccination, it is necessary to check the body temperature and, if this is regular, the first vaccination should be made. In the case in which the body temperature is not regular (fever), the animals must be isolated and treated in advance with antibiotic therapy. Vaccination should then be performed after not less than 1 week since the last antibiotic treatment. In any case, a booster vaccination protocol which foresees a reminder 14 days after the first vaccination is necessary. Animals can be moved again not earlier than 10 days after the second vaccination intervention.

#### *Effectiveness*

##### Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

The implementation of restriction control measures on animal movements and their products, during an infectious outbreak or epidemic, effectively prevents further transmission of the pathogen or new outbreaks of the disease.

#### *Feasibility*

##### Parameter 3 – Feasibility of restriction of animal movement

The underpinning of the disease control programme is an effective surveillance system that provides guidance on priorities and targets for the application of interventions. Restriction measures of animal movement is possible through programmes of vaccination in the affected area, avoid producing and exporting crop soils with high levels of contamination by anthrax spores and reduce animal movements to the site where the outbreak occurred.

### **3.1.4.6. Article 7(d)(vi) Killing of animals**

#### *Availability*

##### Parameter 1 – Available methods for killing animal

Anthrax in animals usually shows a rapid progression with a fatal outcome, so often it is not necessary to kill the animals. It is a very rare event to observe a ruminant in preagonal phase of the disease. However, the preagonal phase of the disease can sometimes be observed in equines affected by anthrax since the course of the disease is slightly longer in equines. Animals generally express in the preagonal phase very serious respiratory symptoms.

#### *Effectiveness*

##### Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

Culling and killing is necessary just in order to avoid suffering in infected animals.

#### *Feasibility*

##### Parameter 3 – Feasibility of killing animals

Where possible, the dead or killed animal must be moved and placed on a floor covered with a durable plastic sheet and subjected to decontaminating treatment. Operators carrying out these operations will necessarily have to take the personal protection measures described above.

### **3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products**

#### *Availability*

##### Parameter 1 – Available disposal option

The primary source of environmental contamination of anthrax spores is from the carcasses of animals that have died of anthrax. To prevent sporulation, carcasses should not be opened. Carcasses should be disposed of intact and the preferred methods used in most countries that practice this method are:

- Burial
- Treatment of carcasses with 10% formalin
- Incineration
- Rendering (effective controlled heat treatment)

In the case of burial (and possibly burning also), consideration may be given to spraying the carcasses and the surrounding ground with 10% formalin to minimise the number of spores which may survive and resurface, presenting infection risk sometimes in the future (Bengis and Frean, 2014). Consideration might be given to treating anthrax carcasses with 10% formalin or 1% peracetic acid leaving them *in situ* for some days before disposal while natural putrefaction processes within the carcass kill the vegetative anthrax organisms. The formalin would have the action of killing anthrax organisms shed by the dead animal, preserving the skin so that it retains the anaerobic environment within the putrefying carcass. It may also deter scavengers that would otherwise open up the carcass and thereby increase the contamination, and flies that might spread the disease. Rendering is essentially a cooking process that results in sterilisation of raw materials of animal origin such those parts of carcasses that may be utilised safely for subsequent commercial purposes. In general, the raw materials are finely chopped and then passed into a steam-heated chamber and subjected to temperatures ranging from 100 to 150°C for 10–60 min (this does not include the time taken to bring the material to the peak temperature or the subsequent cooling period time).

### *Effectiveness*

#### Parameter 2 – Effectiveness of disposal option

##### **Burial**

Periodic reports of viable anthrax spores at burial sites of animals that died many years before support the unreliability of burial procedures for long-term control of the disease. Further disadvantages of burial sites are that scavengers may dig down to reach the carcass, and in dry dusty areas, the digging process can spread the contaminated soil extensively. Furthermore, in raising the pH of the soil, addition of lime when burying anthrax carcasses may actually be counterproductive to minimising long-term spore contamination. In summary, burial should be discouraged in favour of incineration.

##### **Incineration**

Incineration must be carried out with appropriate care to ensure complete burning from beneath. The down directed blow-torch is an alternative incineration procedure that ensures severe scorching of the soil to several centimetres of depth. The spores will be confined to where the blood has been shed through the body orifices and will mostly be in the soil beneath these points. Relatively few spore forms, therefore, will enter the fire and updraft; vegetative forms will almost certainly not survive. If concern persists, consideration might be given to pre-treating the carcass and associated contaminated soil with 10% formalin a few hours before incineration to minimise the number of present viable spores.

##### **Rendering**

The rendering procedure requires the correct performance of each of three stages: collection, transport and treatment of the carcass. These should be supervised by veterinary authorities. It is necessary that the carcass should be bagged and the bag, collection machinery, materials and tools, and the carcass site itself appropriately decontaminated and disinfected. Before heat treatment, carcasses should be broken down into pieces not larger than 10 cm<sup>3</sup>. In the case of anthrax carcasses, this should be done with very careful attention to hygiene during the process, with the necessary disinfection and decontamination of the rendering premises, tools, clothing, waste run-off, etc. Controlled heat-treatment is then carried out with temperature, pressure and time of sterilisation recorded.

### *Feasibility*

#### Parameter 3 – Feasibility of disposal option

The choice of one or more of the recommended methods should be in compliance with relevant local and national legislation and should be attainable with the resources available. In some developing country situations where burial, incineration or rendering is not feasible, the last resort may be to leave the carcass unmoved *in situ* and ensure that it is inaccessible to other animals, particularly



scavengers, or people. This is achieved by covering with tarpaulins, branches of trees, corrugated iron or other available materials. Hazard signs should be posted around sites in this case. This again allows the putrefactive process to take effect, although residual environmental contamination may still remain, and either the site should be scorched after putrefaction is complete or it should be treated with 10% formalin. Alternatively, it should be made inaccessible to other animals indefinitely by fencing, capping with concrete or other impervious material, covering with brushwood, or growing impenetrable undergrowth.

### **3.1.5. Article 7(e) The impact of disease prevention and control measures**

#### **3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole**

##### Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

Not calculable, not definable. It is hypothesised more than one million dollars (US) in the world.

##### Parameter 2 – Cost of eradication (culling, compensation)

Not calculable, not definable. These costs include the expenses of the cost of vaccine and personnel for vaccination campaigns. In areas at risk it is recommended to vaccinate for 10 years.

##### Parameter 3 – Cost of surveillance and monitoring

Not calculable, not definable.

##### Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

Not calculable, not definable.

##### Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

Not calculable, not definable.

#### **3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures**

As for any infectious disease, the outbreaks or individual cases (both animal and human) of anthrax logically trigger concern in society. After the anthrax attack in 2001 in USA, during which some letters containing anthrax spores were mailed to several news media offices and two Democratic US Senators killing five people and infecting 17 others, many things have changed. Obviously this event changed the perceived risk. The control measures (animal vaccination, movement control of animals) have not a big impact on society.

#### **3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals**

In the affected subpopulations, the concern is for the surviving animals. Both in kept and wild animals, surviving animals are vaccinated so that they can graze. Following the vaccination, adverse reactions may occur in the animals.

##### Parameter 1 – Welfare impact of control measures on domestic animals

There is potential for vaccine reaction in vaccinated animals.

##### Parameter 2 – Wildlife depopulation as control measure

Data not available.

#### **3.1.5.4. Article 7(e)(iv) The environment and biodiversity**

##### *Environment*

##### Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

The biocides (sterilising methods based on peracetic acid, sodium hypochlorite, formalin) can be used in proximity to burial sites where animals which died of anthrax are buried.



## Biodiversity

### Parameter 2 – Mortality in wild species

Data not available.

## 3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about anthrax (Table 7). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 13. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 7:** Outcome of the expert judgement on the Article 5 criteria for anthrax

<b>Criteria to be met by the disease:</b> According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		<b>Final outcome</b>
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	NC
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	N
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	Y
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

### 3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Table 8). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

**Table 8:** Outcome of the expert judgement related to criterion 5 B(ii)

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
B(ii) The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	NC	92	8	0

NC: non-consensus; number of judges: 13.

#### Reasoning supporting the judgement

##### Supporting Yes:

- Insurgence of resistance to treatment has been documented in at least two field surveys, e.g. resistance to penicillin in < 1% of strains.
- *In vitro* studies have shown that *B. anthracis* strains can develop resistance to a wide range of antibiotics.
- Any resistance would pose significant dangers to people and animals, i.e. increase mortality rates.

##### Supporting No:

- Resistance of *B. anthracis* strains is not considered to significantly pose a public health risk, and there have been no cases in humans where treatment failed because of resistance of *B. anthracis*.

### 3.2.2. Outcome of the assessment of anthrax according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 7, anthrax complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed as laid down in Article 5 of the AHL.

### 3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about anthrax (Tables 9, 10, 11, 12 and 13). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 13. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 9:** Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for anthrax

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC
2.1	The disease is highly transmissible	N
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	Y

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

**Table 10:** Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for anthrax

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC
2.1	The disease is moderately to highly transmissible	Y
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N

5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

**Table 11:** Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for anthrax

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is present in the whole OR part of the Union territory with an endemic character	NC
2.1	The disease is moderately to highly transmissible	Y
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	N
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	NC
4(CI)	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	N
4(PI)	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	N
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

**Table 12:** Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for anthrax

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
the disease fulfils criteria of Sections 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

**Table 13:** Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for anthrax

Diseases in category E need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL and/or the following:		<b>Final outcome</b>
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

### 3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 14 and 15). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

**Table 14:** Outcome of the expert judgement related to criterion 1 of Article 9

<b>Question</b>		<b>Final outcome</b>	<b>Response</b>		
			<b>Y (%)</b>	<b>N (%)</b>	<b>na (%)</b>
1(cat.A)	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC	46	54	0
1(cat.B)	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC	31	69	0
1(cat.C)	The disease is present in the whole OR part of the Union territory with an endemic character	NC	8	92	0

NC: non-consensus; number of judges: 13.

#### Reasoning supporting the judgement

Supporting Yes for 1 (cat.A):

- The spores are present in the soil in some areas of the EU, but the disease occurs only sporadically, with the results that there are unlikely to be actively infected animals at all times in the MSs. Anthrax does however retain the potential to generate periodic disease cases over long periods of time.

Supporting Yes for 1 (cat.B):

- B. anthracis* spores are very persistent in the environment, and can remain viable for hundreds of years (De Vos, 1990). Several MSs have been free from the disease for several years, however they cannot demonstrate freedom from the pathogen.

Supporting Yes for 1 (cat.C):

- Where spores are present, anthrax can occur anywhere in the EU without an external introduction of the pathogen.

Supporting No for 1 (cat.A,B,C):

- Spores are likely to be present in limited areas in almost all MSs, but the disease is rare. No MS is documented free. None of the categories can apply here.

**Table 15:** Outcome of the expert judgement related to criterion 3 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
3(cat.C) The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	NC	92	8	0

NC: non-consensus; number of judges: 13.

#### Reasoning supporting the judgement

Supporting Yes for 3:

- Even one single fatal human case of anthrax would lead to significant consequences on public health. Epidemics/pandemics seem very unlikely.
- Eating contaminated meat poses a threat to public health.
- There may be a risk for farmers as they can be exposed.

Supporting No for 3:

- If the use for bioterrorism purposes is not considered here (it is tackled in a specific criterion and anthrax should be dealt with as a bioterrorist threat with clearly significant consequences on public health, epidemic or even potential pandemic implications), the significant consequences or threats to food safety are unlikely, since anthrax may lead to sporadic cases, even deaths in groups of animals but neither to significant human health problems nor to food safety issues from a normal control perspective, nor epidemics nor pandemics and thus it would not be routine problem requiring a high level of routine control.

### **3.3.2. Outcome of the assessment of criteria in Annex IV for anthrax for the purpose of categorisation as in Article 9 of the AHL**

As from the legal text of the AHL, a disease is considered to fit in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 9–13. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'.

A description of the outcome of the assessment of criteria in Annex IV for anthrax for the purpose of categorisation as in Article 9 of the AHL is presented in Table 16.



**Table 16:** Outcome of the assessment of criteria in Annex IV for anthrax for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	NC	N	Y	Y	Y	N	N	N	N	N	N
B	NC	Y	Y	Y	N	N	N	N	N	N	N
C	NC	Y	Y	Y	N	NC	N	N	N	N	N
D	Y										
E	Y										

According to the assessment here performed, anthrax complies with the following criteria of the Sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment anthrax complies with criteria 2.2, 2.3 and 2.4, but not with criterion 2.1 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and anthrax does not comply with any of them.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment anthrax complies with criteria 2.1, 2.2 and 2.3, but not with criterion 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and anthrax does not comply with any of them.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment anthrax complies with criteria 2.1, 2.2 and 2.3, but not with criterion 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and anthrax does not comply with criteria 4, 5a, 5b, 5c and 5d and the assessment is inconclusive on compliance with criterion 3.
- 4) To be assigned to category D, a disease needs to comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4, with which anthrax complies.
- 5) To be assigned to category E, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, with which anthrax complies.

### 3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about anthrax. The Article 8(3) criteria are about animal species to be listed, as it reads below:



'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.<sup>1</sup> According to the

**Table 17:** Main animal species to be listed for anthrax according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/Species
Susceptible	Mammalia	Artiodactyla	Bovidae	<i>Bos taurus</i> , <i>Bison bison</i> , <i>Ovis aries</i> , <i>Capra aegagrus</i> , <i>Damaliscus pygargus phillipsi</i>
			Cervidae	Unspecified
			Suidae	<i>Sus scrofa</i>
		Perissodactyla	Equidae	<i>Equus caballus</i>
			Rhinocerotidae	Unspecified
		Proboscidea	Elephantidae	Unspecified
		Carnivora	Ursidae	Unspecified
			Felidae	Unspecified
			Mustelidae	Unspecified
			Canidae	Unspecified
			Procyonidae	Unspecified
			Viverridae	Unspecified
			Eupleridae	Unspecified
			Mephitidae	Unspecified
		Rodentia	Muridae	<i>Rattus</i> , <i>Mus</i>
			Caviidae	<i>Cavia porcellus</i>
		Lagomorpha	Leporidae	Unspecified
		Diprotodontia	Unspecified	
		Primates	Unspecified	Unspecified
	Aves	Gruiformes	Gruidae	Unspecified
		Anseriformes	Anatidae	Unspecified
		Struthioniformes	Struthionidae	Unspecified
	Reptilia	Testudines	Testudinidae	Unspecified
Reservoir	None			
Vectors	None			

mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for anthrax according to the criteria of Article 8(3) of the AHL are as displayed in Table 17.

## 4. Conclusions

**TOR 1:** for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

<sup>1</sup> A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply or/and undergo transformations within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do neither multiply nor transform within the vector, which usually remains infected for shorter time than in biological vectors.

- According to the assessment here performed, anthrax complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

**TOR 2a:** for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

- According to the assessment here performed, anthrax meets the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL.

**TOR 2b:** for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

- According to the assessment here performed, the susceptible animal species that can be considered to be listed for anthrax according to Article 8(3) of the AHL are several species of mammals, birds and reptiles, as reported in Table 17 in Section 3.4 of the present document.

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## Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
AVA	Anthrax Vaccine Adsorbed
AVP	Anthrax Vaccine Precipitated
BA	blood agar
CDC	Centers for Disease Control and Prevention
CFSPH	Center for Food Security and Public Health
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
DALY	Disability-adjusted life year
ELISA	enzyme-linked immunosorbent assay
FDA	Food and Drug Administration
GABRI	Ground Anthrax Bacillus Refined Isolation
ICBA	Individual and Collective Behavioural Aggregation
IgG	immunoglobulin G
IUCN	International Union for Conservation of Nature
MALDI-TOF	matrix assisted laser desorption ionization-time of flight
MS	Member State
OIE	World Organization for Animal Health
PA	protective antigen
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PLET	polymyxin lysozyme EDTA thallos acetate
TNA	toxin neutralising assay
ToR	Terms of Reference
TSMP	trimethoprim sulfamethoxazole methanol polymyxin
TV	trivalent vaccine
WAHID	World Animal health information database